

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-06 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/CAR:JTHYDEN(INFO)

-----020314Z 022357 /66

P 012108Z APR 77
FM SECSTATE WASHDC
TO AMEMBASSY KINGSTON PRIORITY
AMEMBASSY NASSAU

UNCLAS STATE 072038

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, BF, JM

SUBJECT: FDA ADVISORY - SALMONELLA CONTAMINATION OF
SPECIAL DIETARY FOOD PRODUCTS (RECALL F-049/050-7)

1. FDA ADVISES THAT THE FOLLOWING PRODUCTS ARE BEING
RECALLED:

RECALL NO. F-049-7: PRECISION ISOTONIC DIET. NUTRITIONALLY
BALANCED ISOTONIC FORMULA FOR ORAL OR TUBE FEEDING. VAN-
ILLA ARTIFICIAL FLAVOR. DOYLE PHARMACEUTICAL COMPANY,
MINNEAPOLIS, MINNESOTA 55416. NET WEIGHT 2.06 OUNCES
(58.4 GRAMS).

RECALL NO. F-050-7: PRECISION MODERATE NITROGEN DIET.
NUTRITIONALLY COMPLETE LOW-RESIDUE FOOD FOR ORAL OR TUBE
FEEDING. VANILLA OR CITRUS ARTIFICIAL FLAVORS. DOYLE
PHARMACEUTICAL COMPANY, MINNEAPOLIS, MINNESOTA 55416.
NET WEIGHT 2.75 OUNCES (78 GRAMS).

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THESE PRODUCTS ARE INTENDED FOR FEEDING HOSPITAL PATIENTS.
ALL LOTS OF BOTH PRODUCTS CONTAINING THE LETTER "U" I; THE
CODE ARE BEING RECALLED. ALL NEW PRODUCTION TO FOLLOW

RECALL WILL INCLUDE A "Z" TO DESIGNATE IT FROM THE RECAL-
LED PRODUCT.

MANUFACTURER/RECALLING FIRM:

THE DOYLE PHARMACEUTICAL COMPANY
DIVISION OF DELMARK COMPANY
5320 WEST 23RD STREET
MINNEAPOLIS, MINNESOTA 55416

2. REASON FOR RECALL:

SEVERAL LOTS OF PRECISION ISOTONIC DIET WERE SUSPECTED OF CAUSING 4 CASES OF SALMONELLOSIS IN INFANTS IN SAN DIEGO, CALIFORNIA BETWEEN OCTOBER 1976 AND JANUARY 1977. DUE TO A COMMON INGREDIENT, ALL LOTS OF PRECISION MODERATE NITROGEN DIET ARE BEING RECALLED ALTHOUGH NO PROBLEM HAS BEEN ASSOCIATED WITH ITS USE.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED PRODUCT RECALL LETTER ISSUED BY DOYLE PHARMACEUTICAL COMPANY FEBRUARY 16, 1977. LETTER INDICATES THAT RECIPIENTS ARE TO DETERMINE IF THEY HAVE ANY OF SUSPECT LOTS WITH "U" IN THE LOT CODE. IF SO THEY ARE TO DISCONTINUE DISPENSING DESIGNATED LOTS AND RETURN MARKED "ATTENTION: RETURNED GOODS". THEY ARE ALSO TO NOTIFY ANY PATIENT WHO HAS BEEN USING PRODUCT IN THEIR HOME. ANY QUESTIONS WITH RESPECT TO RECALLED PRODUCT SHOULD BE DIRECTED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

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UNIVERSITY HOSPITAL OF WEST INDIES
MORA STREET, ST. ANDREWS
KINGSTON, JAMAICA

RAND MEMORIAL HOSPITAL

FREEPORT, THE BAHAMAS
CHRISTOPHER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Sent Date: 01-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE072038
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770113-1091
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770497/aaaadgfv.tel
Line Count: 106
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: f1928bab-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 25-Jan-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2923385
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - SALMONELLA CONTAMINATION OF SPECIAL DIETARY FOOD PRODUCTS (RECALL F-049/050-7)
TAGS: OGEN, ETRD, EIND, TBIO, BF, JM
To: KINGSTON NASSAU
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/f1928bab-c288-dd11-92da-001cc4696bcc
Review Markings:
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